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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,914	07/26/2001	Gilles Divita	AM-00105.P.1.1-US	1112
35938	7590	03/10/2004	EXAMINER	
BIOTECHNOLOGY LAW GROUP 658 MARSOLAN AVENUE SOLANA BEACH, CA 92075			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER

1653

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,914	Applicant(s) DIVITA ET AL.	
	Examiner Robert A. Wax	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,18-20,25-28,31,40 and 76-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,11,18,20,25-28,40,76-80,83 and 84 is/are rejected.
- 7) ☒ Claim(s) 4,6-10,12,19,31,81 and 82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02072002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of SEQ ID No. 7 in Paper No. 12152003 is acknowledged. SEQ ID No. 7 was searched, no pertinent art was found. Then SEQ ID Nos. 1-6 and 8-12 were searched, no pertinent art was found for any of those sequences either. Therefore, the election of species is now moot.

Information Disclosure Statement

2. The information disclosure statement filed February 7, 2002 has been considered. Please see the attached initialed PTO-1449.

Claim Objections

3. Claims 28, 83 and 84 are objected to because of the following informalities: In claim 28 the term "covelently" appears, obviously this should be amended to read "covalently"; In claims 83 and 84 the term "uM" appears, obviously this should be amended to read " μ M". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5, 11, 18, 20 and 26-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chaloin et al. (Reference D7).

Chaloin et al. teach a synthetic peptide for delivery of nucleic acids to cells having the sequence AcM-G-L-G-L-H-L-L-V-L-A-A-A-L-Q-G-A-S-W-Q-P-K-K-K-R-K-V-Cya. This sequence anticipates the claims as follows. The first hydrophobic locus is M-G-L-G-L, the spacer is H, the second hydrophobic locus is L-L-V-L, the hydrophilic domain is at least K-K-K-R-K and the spacer is at least Q. This covers claims 1, 3, 5, 11 and 18. Claim 20 is anticipated because the peptide is covalently conjugated to an oligonucleotide. Claim 26 is anticipated because of the Cya group on the C-terminal valine. Claim 27 is anticipated because the C-terminal end of the peptide contains K-R-K and claim 28 is anticipated because they covalently conjugate the peptide to Lucifer yellow, a dye. Thus, Chaloin et al. anticipate the above claims.

6. Claims 1-3, 11, 18, 25, 27, 40, 76, 77 and 83 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morris et al. (Reference D24).

Morris et al. (Reference D24) teach a synthetic peptide called MPG having the sequence AcG-A-L-F-L-G-F-L-G-A-A-G-S-T-M-G-A-W-S-Q-P-K-S-K-R-K-V-Cya. They describe MPG as follows. MPG is constituted of two independent domains linked together by a short peptide sequence: (i) a hydrophobic N-terminal domain (residues 1-17: G-A-L-F-L-G-F-L-G-A-A-G-S-T-M-G-A), the sequence of which derives from the glycine-rich region of the fusion sequence of viral gp41 known to be essential both for its membrane fusion activity and structural stabilization, and (ii) a hydrophilic C-terminal domain (residues 21-27: P-K-S-K-R-K-V) which derives from the nuclear localization signal (NLS) of the SV40 large T antigen. With regard to the instant claims, the first hydrophobic locus is A-L-F-L, the spacer is G, the second hydrophobic locus is at least F-L, the hydrophilic domain is P-K-S-K-R-K-V and the spacer is W-S-Q. This covers claims 1-3, 11, 18 and 27. Claims 25 and 76 are anticipated by the teaching at page 2733, last three lines which discuss the "formation of a micro 'particle' of peptide surrounding the oligonucleotide." This constitutes a noncovalent complex. Claim 40 is anticipated by the teaching at page 2731 under the heading "Cell culture and transfections using MPG" which state that the peptide is in PBS buffer, or phosphate buffered saline. Such a vehicle could be considered a pharmaceutical carrier. Claim 77 is anticipated because the oligonucleotide is a therapeutic compound. Claim 83 is anticipated because of the teaching in the same section of a concentration of 10^{-7} M which is the same as 0.1 μ M. Thus, Morris et al. clearly anticipate the above claims.

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. in view of Phelan et al. (Reference D32).

The teachings of Morris et al. have been outlined above.

Phelan et al. teach delivery of functional p53 into a cell by a protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use p53 as the agent to be delivered by the peptide of Morris et al. Motivation to use p53 is provided by the teaching of its importance by Phelan et al.

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One of ordinary skill in the art would have a reasonable expectation of success in view of the demonstrated ability of the peptide of Morris et al. to deliver oligonucleotide to a cell.

Allowable Subject Matter

10. Claims 4, 6-10, 12, 19, 31, 81 and 82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name.

Robert A. Wax
Primary Examiner
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